

**San Diego
Blood Bank**
A Regional Blood Center



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January 17, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

**Re: Draft Compliance Policy Guidance for FDA Staff and Industry: Blood Donor
Incentives Sec.230.150**

To Whom It May Concern:

This letter is to comment on the Office of Regulatory Affairs (ORA) draft guidance for FDA Staff and Industry: Blood Donor Incentives Sec.230.150.

San Diego Blood Bank (SDBB) supports the goal of assisting both FDA staff and blood establishments in protecting the safety of the blood supply and to establish policies with the intent of promoting consistency in the industry. We seek clarification and offer requested input for the following:

Policy

Page 4, paragraph 2 states "It is also not relevant if the incentive goes only to donors who are successful in donation or if donors who present to donate receive the incentive." We respectfully disagree with this statement. By offering an incentive to all people who present at a donation site rather than offering the incentive only to those who successfully donate, we believe removes the motivation to donate merely to receive the incentive. We would argue that this is an important factor when determining if an incentive could cause the unit of blood to be relabeled as from a paid donor.

Policy

Page 2, paragraph 2 states "Monetary payment includes cash, in any amount, or items that are readily convertible to cash." We would like clarification of "readily convertible". Is an item readily convertible to cash if a person must travel a long distance (out of town) to try to sell the item? Does readily convertible apply if a person must spend money, say for instance to advertise an item, in order to try to sell the item?

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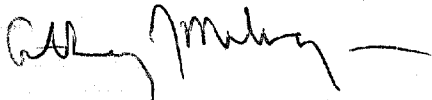
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Policy

Page 5, part G. This paragraph refers to escalating incentive programs. The example given is not clear to SDBB. Is the policy statement indicating that a watch would constitute a donor receiving monetary payment? In our opinion, most watches that are provided as incentives are not readily convertible to cash and would not constitute monetary payment. Please clarify and expand on this example.

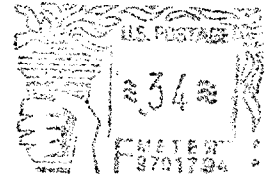
Thank-you for this opportunity to comment on Office of Regulatory Affairs (ORA) draft guidance for FDA Staff and Industry: Blood Donor Incentives Sec.230.150. If you have any questions, please feel free to contact me or the Director, Quality Assurance/Compliance, Ms. Patricia E. Bakke, by phone at (619) 296-6393, or by e-mail at tmelaragno@bloodbank.org or pbakke@bloodbank.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Anthony J. Melaragno', followed by a horizontal line.

Anthony J. Melaragno, M.D.
Medical Director/CEO
San Diego Blood Bank

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